

29964-26

4/2/2014

1/14



**U.S. ENVIRONMENTAL PROTECTION  
AGENCY**

**Office of Pesticide Programs  
Biopesticides and Pollution  
Prevention Division (7511P)  
Ariel Rios Building  
1200 Pennsylvania Ave., NW  
Washington, D.C. 20460**

EPA Reg.

Number:

29964-26

Date of Issuance:

APR 02 2014

## NOTICE OF PESTICIDE:

☒ Registration  
☐ Reregistration  
(under FIFRA, as amended)

Term of Issuance: Conditional

Name of Pesticide Product:

1507xMON810xMIR162 with a 5%  
Blended Refuge

Name and Address of Registrant (include ZIP Code):

Pioneer Hi-Bred International, Inc.

7100 N.W. 62<sup>nd</sup> Avenue

P.O. Box 1000

Johnston, Iowa 50131-1000

**Note: Changes in labeling differing in substance from that accepted in connection with this registration must be submitted to and accepted by the Biopesticides and Pollution Prevention Division prior to use of the label in commerce. In any correspondence on this product always refer to the above EPA registration number.**

On the basis of information furnished by the registrant, the above named pesticide is hereby registered/reregistered under the Federal Insecticide, Fungicide and Rodenticide Act. Registration is in no way to be construed as an endorsement or recommendation of this product by the Agency. In order to protect health and the environment, the Administrator, on his motion, may at any time suspend or cancel the registration of a pesticide in accordance with the Act. The acceptance of any name in connection with the registration of a product under this Act is not to be construed as giving the registrant a right to exclusive use of the name or to its use if it has been covered by others.

This product is conditionally registered in accordance with FIFRA Section 3(c)(5) of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended, provided that you do the following terms.

1] The subject registration will automatically expire on midnight September 30, 2016.

2] Submit/cite all data required for registration of your product under FIFRA § 3(c)(5) when the Agency requires registrants of similar products to submit such data.

-Continued on Page 2-

Signature of Approving Official:

Date:

4/2/2014

Robert McNally, Director

Biopesticides and Pollution Prevention Division (7511P)

EPA Form 8570-6

## CONCURRENCES

SYMBOL	7511P	7511P	7511	7511P				
SURNAME	Hogmes	Reynolds	Nesci	McNally				
DATE	4/2/2014	4/2/2014	4/2/14	4/2/2014				

EPA Form 1320-1A (1/90)

OFFICIAL FILE COPY

3] The subject registration will be limited to a seed mix of Cry1F [*Bacillus thuringiensis* Cry1F protein and the genetic material necessary for its production (plasmid insert PHI8999A) in corn event 1507 (OECD Unique Identifier: DAS-Ø15Ø7-1)] x Cry1Ab [*Bacillus thuringiensis* Cry 1Ab protein and the genetic material (vector PV-ZMBK07) necessary for its production in corn event MON810 (OECD Unique Identifier: MON- ØØ81Ø-6)] x Vip3Aa20 [*Bacillus thuringiensis*-Vip3Aa20 insecticidal protein and the genetic material necessary for its production (via elements of vector pNOV1300) in corn event MIR162 (OECD Unique Identifier: SYN-IR162-4)] blended with not less than 5% non-*Bt* corn seed.

4] Submit/cite all data determined by EPA to be acceptable and required to support the individual plant-incorporated protectant 1507 in 1507xMON810xMIR162 with a 5% Blended Refuge within the timeframes required by the terms and conditions of EPA Registration Numbers 29964-3.

5] Pioneer must implement an Insect Resistance Management Program for 1507xMON810xMIR162 with a 5% Blended Refuge consisting of the following elements:

- Requirements relating to a refuge assurance program for ensuring the correct refuge blend percentage.
- Requirements relating to creation of a lepidopteran refuge (consisting of corn that does not contain any *Bt* trait for lepidopteran control) in cotton growing regions in conjunction with the planting of any acreage of 1507xMON810xMIR162 with a 5% Blended Refuge,
- Requirements for Pioneer to prepare and require 1507xMON810xMIR162 with a 5% Blended Refuge users to sign "grower agreements," that impose binding contractual obligation on the grower to comply with the refuge requirements in cotton growing regions;
- Requirements regarding programs to educate growers about IRM requirements;
- Requirements regarding programs to evaluate and promote growers' compliance with IRM requirements;
- Requirements regarding programs to evaluate whether there are statistically significant and biologically relevant changes in target insect susceptibility to Cry1F, Cry1Ab and Vip3Aa20 proteins in the target insects;
- Requirements regarding a "remedial action plan," that contains measures Pioneer would take in the event that any field-relevant insect resistance was detected as well as to report on activity under the plan to EPA;
- Requirements for Pioneer to maintain and to make available to the Agency upon request the number of units of 1507xMON810xMIR162 with a 5% Blended Refuge sold by state and county, IRM grower agreement results and substantive changes to education programs, within three months of the request;
- Bag Tag Requirements for 1507xMON810xMIR162 with a 5% Blended Refuge. Seed bags and/or bag tags for corn hybrids that contain plant-incorporated protectants produced in 1507xMON810xMIR162 with a 5% Blended Refuge must display the registration number and active ingredients, and stipulate that growers read the Pioneer Stewardship Guide (or equivalent guidance) prior to planting these hybrids. The refuge size requirement must be displayed on the bag or bag tag in both text and graphic format.

### a) Refuge requirements for 1507xMON810xMIR162 with a 5% Blended Refuge

The following information must be included on the product bag or bag-tag as sold per respective region and in the Grower Guide:

#### Corn-Belt/Non-Cotton Growing Areas

1507xMON810xMIR162 with a 5% Blended Refuge contains a Lepidopteran refuge that is “in the bag” and is automatically implemented when the grower plants the product. No additional refuge is required when planting this product.

Foliar insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, beet armyworm, dingy cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, stalk borer and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests.

#### Cotton-Growing Region Refuge Requirements

In cotton-growing regions where corn earworm is a significant pest:

- The 20% refuge must be planted with non-*Bt* corn hybrids.
- 1507xMON810xMIR162 with a 5% Blended Refuge and the 20% non-*Bt* refuge should be sown on the same day, or with the shortest window possible between planting dates.
- External refuges may be planted as an in-field or adjacent (e.g., across the road) refuge or as a separate block within 1/2 mile of the 1507xMON810xMIR162 with a 5% Blended Refuge field.
- In field refuge options include: blocks, perimeter strips (i.e., along the edges or headlands), or in-field strips.
- When planting the refuge in strips across the field, refuges must be at one (1) row wide.
- Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, beet armyworm, dingy cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, stalk borer and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Microbial *Bt* insecticides must not be applied to non-*Bt* corn refuge plants.
- Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greensville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

When on-farm assessments identify non-compliance with refuge requirements for one or more *Bt* corn products, additional educational material and assistance are provided by Pioneer to help these growers meet the refuge

requirements across their farming operations.

**b) Grower agreement for 1507xMON810xMIR162 with a 5% Blended Refuge**

1. Persons purchasing 1507xMON810xMIR162 with a 5% Blended Refuge must sign a grower agreement. The term "grower agreement" refers to any grower purchase contract, license agreement, or similar legal document.
2. The grower agreement and/or specific stewardship documents referenced in the grower agreement must clearly set forth the terms of the current IRM program. By signing the grower agreement, a grower must be contractually bound to comply with the requirements of the IRM program.
3. Pioneer must integrate this registration into the current system used for previously registered Pioneer *Bt* corn products, which is reasonably likely to assure that persons purchasing 1507xMON810xMIR162 with a 5% Blended Refuge will affirm annually that they are contractually bound to comply with the requirements of the IRM program.
4. Pioneer must integrate this registration into the current system which is used for its other *Bt* corn plant-incorporated protectants and which is reasonably likely to assure that persons purchasing 1507xMON810xMIR162 with a 5% Blended Refuge sign grower agreement(s).
5. Pioneer shall maintain records of all 1507xMON810xMIR162 with a 5% Blended Refuge grower agreements for a period of three years from December 31<sup>st</sup> of the year in which the agreement was signed.
6. Pioneer shall maintain and make available to the Agency upon request records of the number of units of 1507xMON810xMIR162 with a 5% Blended Refuge seed sold by state and county, and the number of such units that were sold to persons who have signed grower agreements within three months of the request.
7. Pioneer must allow a review of the grower agreements and grower agreement records by EPA or by a State pesticide regulatory agency if the State agency can demonstrate that confidential business information, including names, personal information, and grower license number, will be protected.

**c) IRM Education and IRM Compliance Monitoring Program for 1507xMON810xMIR162 with a 5% Blended Refuge in EPA-designated cotton counties**

1. Pioneer must implement and enhance a comprehensive, ongoing IRM education program designed to convey 1507xMON810xMIR162 with a 5% Blended Refuge users the importance of complying with the IRM program. The program must also address unexpected pest damage and guidance for growers in this area. The education program shall involve the use of multiple media, *e.g.* face-to-face meetings, mailing written materials, EPA-reviewed language on IRM requirements on the bag or bag tag, and electronic communications such as by internet, radio, or television commercials. Copies of the materials will be provided to EPA for their records. The program shall involve at least one written communication annually to each 1507xMON810xMIR162 with a 5% Blended Refuge user separate from the grower technical guide. The communication shall inform the user of the current IRM requirements and specifically the need to plant a lepidopteran refuge in cotton growing regions. Pioneer shall

coordinate its education program with the educational efforts of other registrants and other organizations, such as the National Corn Growers Association and state extension programs.

2. Pioneer must design and immediately implement a "bag tag" that will be attached to all bags of 1507xMON810xMIR162 with a 5% Blended Refuge seed sold and delivered for the 2015 growing season and annually thereafter. The purpose of this bag tag is to remind growers that 1507xMON810xMIR162 with a 5% Blended Refuge products require a separate 20% lepidopteran refuge in cotton-growing areas. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. A revised PIP product label must be submitted by January 31, 2015.
3. Pioneer must conduct targeted, on-farm compliance assessments for growers who purchase 1507xMON810xMIR162 with a 5% Blended Refuge seed to ensure growers are compliant with the requirement of a 20% refuge for lepidopteran pests in cotton growing areas. Results of these on-farm surveys must be reported separately from non-seed blended products.

Pioneer must provide, in conjunction with other Pioneer PIP products, a report to EPA summarizing the 1507xMON810xMIR162 with a 5% Blended Refuge compliance assurance program activities and results for the prior year and plans for the 1507xMON810xMIR162 with a 5% Blended Refuge compliance assurance program for the current year, by January 31, 2015, and annually thereafter. Within one month of submitting this report to EPA, Pioneer shall meet with EPA to discuss its findings. The report must inform EPA of the number of growers deemed ineligible to purchase *Bt* corn seed on the basis of continued non-compliance with the insect resistance management refuge requirements.

4. Pioneer shall implement and enhance its education program to take into account the information collected through the compliance survey and from other sources. The changes shall address aspects of grower compliance that are not sufficiently high.
5. Pioneer must maintain and provide to the Agency upon request, substantive changes to educational programs within three months of the Agency's request.
6. Pioneer shall revise and expand its existing Compliance Assurance Program to include the following elements: Pioneer must prepare and submit a written description of its revised Compliance Assurance Program. Pioneer may coordinate with other registrants in designing and implementing its Compliance Assurance Program.
7. Pioneer will enhance the refuge education program throughout the seed delivery channel:
  - i. Ensure sales representatives, licensees, seed dealers, and growers recognize the importance of correct refuge implementation and potential consequences of failure to plant the required refuge;
  - ii. Pioneer must design and immediately implement a "bag tag" that will be attached to all bags of 1507xMON810xMIR162 with a 5% Blended Refuge seed sold and delivered for the 2014 growing season and annually thereafter. The purpose of this bag tag is to remind growers that 1507xMON810xMIR162 with 5% Blended Refuge products require a separate 20% lepidopteran refuge in cotton growing areas. The PIP product label accepted by EPA must include how this information will be conveyed to growers via text and graphics. A revised PIP product label must be submitted by January 31, 2015.

8. Pioneer will focus the majority of on-farm assessments on regions with the greatest risks for resistance:
  - i. Use *Bt* corn adoption, pest pressure information, and other available information to identify regions where the risk of resistance is greatest;
  - ii. Focus approximately two-thirds of on-farm assessments on these regions, with the remaining assessments conducted across other regions 1507xMON810xMIR162 with a 5% Blended Refuge is used.
9. Pioneer will use its available 1507xMON810xMIR162 with a 5% Blended Refuge sales records and other information to refine grower lists for on-farm assessments of their compliance with refuge requirements:
  - i. Identify for potential on-farm assessment growers whose sales information indicates they have purchased the 1507xMON810xMIR162 with a 5% Blended Refuge but may have purchased little or no refuge seed from the registrant, licensee, or affiliated companies.
10. Pioneer will contract with third parties to perform on-farm assessments of compliance with refuge requirements:
  - i. A third party is classified as a party other than the registrant, the grower, or anyone else with a direct interest in IRM compliance for *Bt* corn.
  - ii. The third-party assessors will conduct all first-time on-farm assessments for as well as second-year on-farm assessments of those growers found out of compliance in a first-time assessment.
11. Pioneer will annually refine the on-farm assessment program for the 1507xMON810xMIR162 with a 5% Blended Refuge to reflect the adoption rate and level of refuge compliance for 1507xMON810xMIR162 with a 5% Blended Refuge.
12. Pioneer will follow up with growers who have been found significantly out of compliance under the on-farm assessment program and are found to be back in compliance the following year:
  - i. All growers found to be significantly out of compliance in a prior year will annually be sent additional refuge assistance information for a minimum of two years by Pioneer, a seed supplier, or a third party assessor, after completing the assessment process;
  - ii. Pioneer will conduct follow-up checks on growers found to be significantly out of compliance within three years after they are found to be back in compliance;
  - iii. A grower found with a second incident of significant non-compliance with refuge requirements for 1507xMON810xMIR162 with a 5% Blended Refuge within a five-year period will be denied access to Pioneer's *Bt* corn products the next year. Similarly, seed dealers who are not fulfilling their obligations to inform/educate growers of their IRM obligations will lose their opportunity to sell *Bt* corn.

**d) Insect Resistance Monitoring and Remedial Action Plan for 1507xMON810xMIR162 with a 5% Blended Refuge**

***EPA is imposing the following conditions for the Cry1F Cry1Ab and Vip3Aa20 toxins expressed in 1507xMON810xMIR162 with a 5% Blended Refuge:***

Pioneer will monitor for resistance to its lepidopteran-resistant *Bt* corn. The monitoring program shall consist of two approaches: (1) focused population sampling and laboratory testing; and (2) investigation of reports of less-than expected control of labeled insects. Should field-relevant resistance be confirmed, an appropriate resistance management action plan will be implemented

**(1) Focused Population Sampling**

Pioneer shall annually sample and bioassay populations of the key target pests *Ostrinia nubilalis* (European corn borer; ECB), *Diatraea grandiosella* (Southwestern corn borer; SWCB), and *Helicoverpa zea* (corn earworm; CEW). Sampling for the target pests will be focused in areas identified as those with the highest risk of resistance development (e.g., where lepidopteran-active *Bt* hybrids are planted on a high proportion of the corn acres, and where the insect species are regarded as key pests of corn). Bioassay methods must be appropriate for the goal of detecting field-relevant shifts in population response to lepidopteran resistant *Bt* corn and/or changes in resistance allele frequency in response to the use of *Bt* corn and, as far as possible, should be consistent across sampling years to enable comparisons with historical data.

The number of populations to be collected shall reflect the regional importance of the insect species as a pest, and specific collection regions will be identified for each pest. For ECB, a minimum of 12 populations across the sampling region will be targeted for collection at each annual sampling. For SWCB, the target will be a minimum of six populations. For CEW, the target will be a minimum of 10 populations. Pest populations should be collected from multiple corn-growing states reflective of different geographies and agronomic conditions. To obtain sufficient sensitivity to detect resistance alleles before they become common enough to cause measurable field damage, each population collection shall attempt to target 400 insect genomes (egg masses, larvae, mated females, and/or mixed-sex adults), but a successful population collection will contain a minimum of 100 genomes. It is recognized that it may not be possible to collect the target number of insect populations or genomes due to factors such as natural fluctuations in pest density, environmental conditions, and area-wide pest suppression.

The sampling program and geographic range of collections may be modified as appropriate based on changes in pest importance and for the adoption levels of lepidopteran-resistant *Bt* corn. The Agency shall be consulted prior to the implementation of such modifications.

The registrant will report to the Agency before August 31 each year the results of the population sampling and bioassay monitoring program.

Any incidence of unusually low sensitivity to the *Bt* protein in bioassays shall be investigated as soon as possible to understand any field relevance of such a finding. Such investigations shall proceed in a stepwise manner until the field relevance can be either confirmed or refuted, and results of these shall be reported to the Agency annually before August 31. The investigative steps will include:

1. Re-test progeny of the collected population to determine whether the unusual bioassay response is reproducible and heritable. If it is not reproducible and heritable, no further action is required.
2. If the unusual response is reproducible and heritable, progeny of insects that survive the diagnostic concentration will be tested using methods that are representative of exposure to *Bt* corn hybrids under field conditions. If progeny do not survive to adulthood, any suspected resistance is not field relevant and no further action is required.

3. If insects survive steps 1 and 2, resistance is confirmed, and further steps will be taken to evaluate the resistance. These steps may include:

- determining the nature of the resistance (*i.e.*, recessive or dominant, and the level of functional dominance);
- estimating the resistance-allele frequency in the original population;
- determining whether the resistance-allele Frequency is increasing by analyzing field collections in subsequent years sampled from the same site where the resistance allele(s) was originally collected;
- determining the geographic distribution of the resistance allele by analyzing field collections in subsequent years from sites surrounding the site where the resistance allele(s) was originally collected.

Should field-relevant resistance be confirmed, and the resistance appears to be increasing or spreading, the registrant will consult with the Agency to develop and implement a case-specific resistance management action plan.

## **(2) Investigation of Reports of Unexpected Levels of Damage by the Target Pests:**

The registrant will follow up on grower, extension specialist or consultant reports of unexpected levels of damage by the lepidopteran pests listed on the pesticide label. The registrant will instruct its customers to contact them if such incidents occur. The registrant will investigate all legitimate reports submitted to the company or the company's representatives.

If reports of unexpected levels of damage lead to the suspicion of resistance in any of the key target pests (ECB, SWCB, and CEW), the registrant will implement the actions described below, based on the following definitions of *suspected resistance* and *confirmed resistance*.

### *Suspected resistance*

EPA defines *suspected resistance* to mean field reports of unexpected levels of insect feeding damage for which:

- the corn in question has been confirmed to be lepidopteran-active *Bt* corn;
- the seed used had the proper percentage of corn expressing *Bt* protein;
- the relevant plant tissues are expressing the expected level of *Bt* protein; and
- it has been ruled out that species not susceptible to the protein could be responsible for the damage, that no climatic or cultural reasons could be responsible for the damage, and that there could be no other reasonable causes for the damage.

The Agency does not interpret *suspected resistance* to mean grower reports of possible control failures or suspicious results from annual insect monitoring assays, nor does the Agency intend that extensive field studies and testing be undertaken to confirm scientifically the presence of insects resistant to *Bt* corn in commercial production fields before responsive measures are undertaken.

If resistance is *suspected*, the registrant will instruct growers to do the following:



- Use alternative control measures in the *Bt* corn fields in the affected region to control the target pest during the immediate growing season.
- Destroy *Bt* corn crop residues in the affected region within one month after harvest with a technique appropriate for local production practices to minimize the possibility of resistant insects over-wintering and contributing to the next season's target pest population.

Additionally, if possible, and prior to the application of alternative control measures or destruction of crop residue, the registrant will collect samples of the insect population in the affected fields for laboratory rearing and testing. Such rearing and testing shall be conducted as expeditiously as practical.

### *Confirmed resistance*

EPA defines *confirmed resistance* to mean, in the case of field reports of unexpected levels of damage from the key target pests, that all the following criteria are met:

- There is >30% insect survival and commensurate insect feeding in a bioassay, initiated with neonate larvae, that uses methods that are representative of exposure to *Bt* corn hybrids under field conditions (ECB and SWCB only).
- In standardized laboratory bioassays using diagnostic concentrations of the *Bt* protein suited to the target pest in question, the pest exhibits resistance that has a genetic basis and the level of survivorship indicates that there may be a resistance allele frequency of  $\geq 0.1$  in the sampled population.
- In standardized laboratory bioassays, the  $LC_{50}$  exceeds the upper limit of the 95% confidence interval of the  $LC_{50}$  for susceptible populations surveyed both in the original baselines developed for this pest species and in previous years of field monitoring.

### **(3) Response to Confirmed Resistance in a Key Target Pest as the Cause of Unexpected Levels of Damage in the Field**

When field resistance is *confirmed* (as defined above), the following steps will be taken by the registrant:

- EPA will receive notification within 30 days of resistance confirmation;
- Affected customers and extension agents will be notified about confirmed resistance within 30 days;
- Monitoring will be increased in the affected area and local target pest populations will be sampled annually to determine the extent and impact of resistance;
- If appropriate (depending on the resistant pest species, the extent of resistance, the timing of resistance, and the nature of resistance, and the availability of suitable alternative control measures), alternative control measures will be employed to reduce or control target pest populations in the affected area. Alternative control measures may include advising customers and extension agents in the affected area to incorporate crop residues into the soil following harvest to minimize the possibility of over-wintering insects, and/or applications of chemical insecticides;
- Unless otherwise agreed with EPA, stop sale and distribution of the relevant lepidopteran-active *Bt* corn

hybrids in the affected area immediately until an effective local mitigation plan approved by EPA has been implemented;

- The registrant will develop a case-specific resistance management action plan within 90 days according to the characteristics of the resistance event and local agronomic needs. The registrant will consult with appropriate stakeholders in the development of the action plan, and the details of such a plan shall be approved by EPA prior to implementation;
- Notify affected parties (e.g. growers, consultants, extension agents, seed distributors, university cooperators and state/federal authorities as appropriate) in the region of the resistance situation and approved action plan; and
- In subsequent growing seasons, maintain sales suspension and alternative resistance management strategies in the affected region(s) for the *Bt* corn hybrids that are affected by the resistant population until an EPA-approved local resistance management plan is in place to mitigate the resistance.

A report on results of resistance monitoring and investigations of damage reports must be submitted to the Agency annually by August 31<sup>st</sup> each year for the duration of the conditional registration.

**e) Refuge Assurance Program for 1507xMON810xMIR162 with a 5% Blended Refuge**

Pioneer must implement a Blended Seed Refuge Assurance Program designed to ensure 1507xMON810xMIR162 with a 5% Blended Refuge products are formulated with the appropriate rate of refuge seeds. The program must include the following four elements:

1. Trait purity check on seed lots prior to blending;
2. -ISO certified Standard Operating Procedures for the blending process;
3. Calibration of blending equipment; and
4. Records and data retention records for seed blend products.
  - Calibration records - Pioneer will retain documentation for a specified period of time on the equipment calibration including the procedure, when it was conducted and the results.
  - Blend proportion records (weight and kernel based) - Pioneer will retain documentation for a specified period of time on the kernel per pound data of the components, the calculations to determine the proportions based on weight and the actual weights that are blended together to make up an 1507xMON810xMIR162 with a 5% Blended Refuge product by seed lot.

All records must be maintained at the Pioneer blending facility and must be available for the EPA review upon request.

**f) Annual Reporting Requirements 1507xMON810xMIR162 with a 5% Blended Refuge**

1. Compliance Assurance Program: compliance assurance program activities, including IRM Grower Survey and on-farm assessment results for the prior year and plans for the compliance assurance

11/14

program for the current year, on or before January 31<sup>st</sup> each year beginning in 2016;

2. Insect Resistance Monitoring Results: results of monitoring and investigations of damage reports, on or before August 31<sup>st</sup> each year.

A copy of the stamped label is enclosed for your records.

The basic confidential statement of formula (CSF) dated 12/13/13 is acceptable. It supersedes all previously submitted basic CSFs. A copy has been placed in the file jacket for this registration.

Sincerely,



Robert McNally, Director  
Biopesticides and Pollution  
Prevention Division (7511P)

Enclosure

12/14

## 1507xMON810xMIR162 with a 5% Blended Refuge

(OECD Unique Identifier: DAS-Ø15Ø7-1xMON-ØØ81Ø-6xSYN-IR162-4)

### Active Ingredients

*Bacillus thuringiensis* Cry1F protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1..... ≤0.0017%\*

*Bacillus thuringiensis* Cry1Ab protein and the genetic material (vector PV-ZMBK07) necessary for its production in corn event MON-ØØ81Ø-6..... ≤0.0013%\*

*Bacillus thuringiensis* Vip3Aa20 protein and the genetic material (via elements of pNOV1300) necessary for its production in corn event SYN-IR162-4..... ≤0.02%\*

### Inert Ingredients

Phosphinothricin acetyltransferase (PAT) protein and the genetic material (plasmid insert PHI8999A) necessary for its production in corn event DAS-Ø15Ø7-1..... ≤0.00046%\*

Phosphomannose isomerase (PMI) protein and the genetic material (via elements of pNOV1300) necessary for its production in corn event SYN-IR162-4..... ≤0.00048%\*

\* Percentage (wt/wt) on a dry wt. basis for whole plant (forage).

KEEP OUT OF REACH OF CHILDREN

CAUTION

NET CONTENTS \_\_\_\_\_

EPA REGISTRATION NUMBER: 29964-xx

EPA ESTABLISHMENT NUMBER: 029964-IA-001

Pioneer Hi-Bred International, Inc.  
7300 NW 62<sup>nd</sup> Avenue  
Johnston, IA 50131

**ACCEPTED**

APR 02 2014

Under the Federal Insecticide, Fungicide,  
and Rodenticide Act, as amended, for  
the pesticide registered under  
EPA Reg. No. 29964-26

13/14

## DIRECTIONS FOR USE

It is a violation of Federal law to use this product in any manner inconsistent with its labeling.

The plant-incorporated protectant must be used as specified in the terms and conditions of the registration.

This plant-incorporated protectant (PIP) may be combined through conventional breeding with other registered plant-incorporated protectants that are similarly approved for use in combination, through conventional breeding, with other registered plant-incorporated protectants to produce inbred corn lines and hybrid corn varieties with combined pesticidal traits.

1507xMON810xMIR162 with a 5% Blended Refuge corn consists of 95% 1507xMON810xMIR162 and 5% non-*Bt* seed blended together in a seed bag. This product controls above ground lepidopteran pests of maize and the blended non-*Bt* plants provide refuge for lepidopteran pests.

## INSECT RESISTANCE MANAGEMENT

Growers are instructed to read information on insect resistance management.

These refuge requirements do not apply to seed increase/propagation of inbred and hybrid seed corn up to a total of 20,000 acres per county and up to a combined United States (U.S.) total of 250,000 acres per plant-incorporated protectant active ingredient per registrant per year.

The following information regarding commercial production must be included in the grower guides for cotton and non-cotton growing areas:

Corn seed bags or bag tags for products containing 1507xMON810xMIR162 with a 5% Blended Refuge must include the refuge size requirement in text and graphical format.

### Corn-Belt/Non-Cotton Growing Areas

1507xMON810xMIR162 with a 5% Blended Refuge contains a Lepidopteran refuge that is "in the bag" and is automatically implemented with the grower plants the product. No additional refuge is required when planting this product in non-cotton areas of the United States.

Foliar insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, and sugarcane borer may be applied only if economic thresholds are reached for one or more of these target pests. Foliar insecticide treatments are also permitted for control of corn rootworm adults if economic thresholds are reached. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g. Extension Service agents, crop consultants).

### Cotton Growing Region Refuge Requirements

In cotton-growing regions where corn earworm is a significant pest:

- An additional 20% structured refuge must be planted with non-*Bt* corn hybrids
- 1507xMON810xMIR162 with a 5% Blended Refuge and the 20% non-*Bt* refuge seed should be sown on the same day, or with the shortest window possible between planting dates
- External refuges may be planted as an in-field or adjacent (e.g. across the road) refuge or as a separate block within 1/2 mile of the 1507xMON810xMIR162 with a 5% Blended Refuge field(s).

14/14

- In field refuge options include: blocks, perimeter strips (*i.e.*, along the edges or headlanes), or in-field strips.
- When planting the refuge in strips across the field, refuges must be at least four (4) rows wide.
- Insecticide treatments for control of European corn borer, corn earworm, southwestern corn borer, fall armyworm, black cutworm, stalk borer, western bean cutworm, lesser corn stalk borer, southern corn stalk borer, sugarcane borer, beet armyworm and dingy cutworm may be applied only if economic thresholds are reached for one or more of these target pests. Economic thresholds will be determined using methods recommended by local or regional professionals (e.g., Extension Service agents, crop consultants). Microbial *Bt* insecticides must not be applied to non-*Bt* corn and/or non-lepidopteran resistant *Bt* corn refuges.
- Cotton-growing areas include the following states: Alabama, Arkansas, Georgia, Florida, Louisiana, North Carolina, Mississippi, South Carolina, Oklahoma (only the counties of Beckham, Caddo, Comanche, Custer, Greer, Harmon, Jackson, Kay, Kiowa, Tillman, Washita), Tennessee (only the counties of Carroll, Chester, Crockett, Dyer, Fayette, Franklin, Gibson, Hardeman, Hardin, Haywood, Lake, Lauderdale, Lincoln, Madison, Obion, Rutherford, Shelby, and Tipton), Texas (except the counties of Carson, Dallam, Hansford, Hartley, Hutchinson, Lipscomb, Moore, Ochiltree, Roberts, and Sherman), Virginia (only the counties of Dinwiddie, Franklin City, Greenville, Isle of Wight, Northampton, Southampton, Suffolk City, Surrey, Sussex) and Missouri (only the counties of Dunklin, New Madrid, Pemiscot, Scott, Stoddard).

Crop	Pests
Field Corn	black cutworm beet armyworm corn earworm dingy cutworm European corn borer fall armyworm southwestern corn borer western bean cutworm lesser corn stalk borer southern corn stalk borer stalk borer sugarcane borer